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PATENT COOPERATION TREATY

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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ----	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB 03/05323	International filing date *(day/month/year)* 05.12.2003	Priority date *(day/month/year)* 06.12.2002
International Patent Classification (IPC) or both national classification and IPC C07K7/06, C07K7/00		
Applicant SINGAPORE GENERAL HOSPITAL PTE LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14.06.2004	15.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Groenendijk, M Telephone No. +31 70 340-3715

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/05323

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-50 as originally filed

Claims, Numbers

1-56 as originally filed

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☒ contained in the international application in written form.

   ☒ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 15,16 as to IA;1-29,53-56(all partially);30-52(all complete)

   because:

   ☒ the said international application, or the said claims Nos. 15,16 as to IA relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 1-29,53-56(all partially); 30-52(all complete)

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/ or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-4,14-25,28,29,56
	No:	Claims	5-13,26,27,53-55
Inventive step (IS)	Yes:	Claims	1-4,14-25,28,29,56
	No:	Claims	5-13,26,27,53-55
Industrial applicability (IA)	Yes:	Claims	1-14,17-29,53-56
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1)Claims 15 and 16 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

2)Due to lack of unity as discussed in the ISR, and the fact that no additional fees have been paid the search has been restricted to the first subject, that is, peptide having SEQ ID NO. 1, peptides up to 60 amino acids comprising it or at least 5 amino acid residues thereof in corresponding positions; their compositions and use in the treatment of CNS damage, spinal cord injury or stroke; their use in designing mimetics inhibiting NOGO, MAG or TN-R; bacteriophage containing them and its use in identifying similar mimetics; use of said mimetics in the same treatment (claims 1-29 and 53-56: all partially).
The initial phase of the search as to claims 5-7 revealed a very large number of documents (ca.500) relevant to the issue of novelty. So many documents were retrieved that it is impossible to determine which parts of said claims may be said to define subject-matter for which protection might legitimately be sought (Art.6 PCT). For these reasons a meaningful search over the whole breadth of said claims is impossible. Consequently the search has been directed to peptides up to 60 aa residues comprising SEQ ID NO. 1.
Furthermore the claims 25 and 29 are so-called "two-step process claims" comprising two distinct types of process claims: the second process is of the production type but it starts with undefined starting materials from the first process, rendering said claims unclear under Art.6. Hence only the first process of said claims has been the subject of a search.
In view of Rule 66.1(e) PCT also the examination will be directed to said subject-matter and extended to claims 5-7 and related claims with a restricted number of documents retrieved in the initial phase of the search.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1:WO-A-9702344
D2:Database EMBL; accession nr.: Q9BDQ2
D3:WO-A-0151520

I.Novelty

1)Document D1 discloses the polypeptide IYLTQPKIKV and its pharmaceutical composition (see SEQ ID NO. 8, claim 4), rendering the claims 5,6,8-13,26,27 and 53-55 not novel under Art.33(2) PCT.
2)D2 discloses the polypeptide TCELIYLTQPSSS. In view of this document the claims 5-11,26 and 27 are considered to lack novelty under Art.33(2) PCT.

II.Inventive step

1)The document D3 is regarded as being the closest prior art to the subject-matter of claim 1 and discloses ligands to NOGO which inhibit the axonal growth inhibiting activity of NOGO and their use in the treatment of CNS/spinal cord damage.
2)The subject-matter of claim 1, i.e. the polypeptide having the sequence of SEQ ID NO.1, differs structurally from said prior art and is used for the same purpose.
3)The problem to be solved by the present invention may be regarded as the provision of alternative polypeptides for the treatment of CNS/spinal cord damage.
4)The solution to this problem proposed in claims 1-4 of the present application has not been indicated or suggested in the prior art and therefore is considered as involving an inventive step (Article 33(3) PCT).

Claims 14-25,28,29 and 56 are dependent on said claims and as such also meet/s the requirements of the PCT with respect to novelty and inventive step.

For the assessment of the present claims 15 and 16 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.